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10/508,810	09/22/2004	Hiroshi Otsuki	59150-8031	9688
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PERKINS COIE LLP P.O. BOX 2168 MENLO PARK, CA 94026			EXAMINER BAGGOT, BRENDAN O	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/508,810

Applicant(s)

OTSUKI ET AL.

Examiner

Brendan O. Baggot

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1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 16-21, 23, 24, 26 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-15, 22 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 9/14/06.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Restriction / Election*

1. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/2/07.
2. Claims 16-21, 23-24 and 26-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 23, 24, 26, and 27 are withdrawn from further consideration because the claims are drawn to non-elected sequences.
3. Applicant's election with traverse of Group I, claims 1-15 and 22-27 drawn to SEQ ID NO: 1 in the reply filed on 8/2/07 is acknowledged. The traversal is primarily on the ground(s) that Aharoni does not teach the technical feature and Aharoni does not teach the use any of specific promoters or assessing the expression patterns of promoters. Instead the Response asserts that Aharoni teaches assessing gene expression. (Response, page 3). This is not found persuasive because gene expression *requires* the gene be operably linked to a promoter. The expression measured by Aharoni must have been driven by one or more promoters. Thus Aharoni does indeed assess promoter expression by assessing differential transcript expression levels. Thus, given Aharoni, the claimed invention lacks a special technical feature. Furthermore, Applicant is reminded that it is the province and duty of the Examiner to say what the technical feature is. While a search of the prior art for one group may overlap with that of another group, they are not co-extensive of each other and thus would represent undue burden on Office resources.

4. The requirement is still deemed proper and is therefore made FINAL.
5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
6. Claims 1-15, 22 and 25 are examined in the instant application.

#### ***Specification***

7. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See M.P.E.P. § 608.01. See pages 33 and 36, for example.
8. The disclosure is objected to because the specification refers to SEQ ID NO: 1 as CG0060\_1 (page 48, line 25; page 56, line 4) and Figures 4 & 5 recite 50060. Clarification and or correction as to which sequence is described by SEQ ID NO: 1 is required.
9. The drawings are similarly objected to for apparently inconsistent recitations referring to SEQ ID NO: 1.

***Claim Rejections - 35 U.S.C. §112, second paragraph lack of definiteness***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-15, 22 and 25 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claims 1, 8, and 12 recite the limitation "is determined". The metes and bounds of "is determined " is unclear because it is unclear whether the specificity is being controlled by the expression frequency or whether "determined" refers to the action of the artisan in assigning a value for promoter specificity. For the purposes of examination, the Office will interpret the claim as having the latter meaning. Appropriate correction is required.

Claim 1 recites gene operably linked to a promoter and expression frequency of the gene including the promoter. It is unclear whether gene is meant to include the promoter in accordance with the first usage in claim 1 or whether gene is meant to refer to the structural gene in accordance with the 2nd usage in claim 1.

Those claims not specifically addressed in this rejection are indefinite because they depend from an indefinite claim.

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph, lack of written description***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to any promoter of any length and sequence from any source, promoter-GFP expression libraries, SEQ ID NO: 1, and cassettes and plants recombined or transformed therewith respectively. (Claim 1 and its dependents)

Applicants describe only SEQ ID NO: 1 and a cDNA library. (See sequence listing and examples 4, 7).

Applicants do not describe any promoter of any length and sequence from any source, promoter-GFP expression libraries, or cassettes and plants recombined or transformed therewith respectively.

"[O]ne promoter", recited in claim 1, is interpreted as any promoter of any length and sequence from any source.

"[A] cDNA database in which the gene including the promoter is included" is interpreted to mean a promoter expression library.

Claims 1-15 lack adequate written description because SEQ ID NO: 1 is not representative of any promoter of any length and sequence from any source. The claims encompass all promoters, yet no structural variants have been disclosed. The

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claims also encompass promoters from other species which when operably linked to a structural gene can initiate transcription. The implication is that there is a promoter other than that disclosed which exists in nature, but the structure thereof is not known.

Furthermore, Claims 1-15 lack adequate written description because Applicants fail to describe structural features common to members of the claimed genus of any promoter. One skilled in the art cannot predictably determine the structure of any promoter of any length and sequence from any source based upon the mere disclosure of SEQ ID NO: 1. One sequence, SEQ ID NO: 1, is not a complete description of the genus of any promoter. Accordingly, there is a lack of written description of the claimed genus.

Furthermore, given the lack of description of the necessary elements essential for any promoter, it remains unclear what features identify any promoter. Since the genus of any promoter has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

Accordingly, the specification fails to provide an adequate written description to support the genus of any promoter encompassed by the hybridization language or percent identity language as set forth in the claims. (See Written Description guidelines published in Federal Register/Vol. 66, No.4/Friday, January 5, 2001/Notices: p.1099-1111).

***Claim Rejections - 35 U.S.C. §112, first paragraph, lack of enablement***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 1, does not reasonably provide enablement for any promoter of any length and sequence from any source, promoter-GFP expression libraries, or cassettes and plants recombined or transformed therewith respectively. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The *Wands* court set forth the enablement balancing test:

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). *Wands* states at page 1404, "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the 'claims.'"

The claims are broadly drawn to any promoter of any length and sequence from any source, promoter-GFP expression libraries, SEQ ID NO: 1, and cassettes and plants recombined or transformed therewith respectively. (Claim 1 and its dependents)

Applicants teach only SEQ ID NO: 1 and a cDNA library. (See sequence listing and examples 4, 7).



Applicants do not teach any promoter of any length and sequence from any source, promoter-GFP expression libraries, or cassettes and plants recombined or transformed therewith respectively.

No guidance has been provided on how to identify sequences from other species. No guidance has been provided on how to rule out all those sequences which are not expressed in rice. No guidance has been provided on how to make a promoter expression library with unknown promoter sequences.

The state-of-the-art is such that one of skill in the art cannot predict the sequence of any and all unknown promoters. There is abundant prior art to suggest that promoter identification is difficult, unpredictable and unsuccessful. Recent reviews by Fickett by Hauschild, detail a variety of problems seen in promoter identification.

The state of the prior art as exemplified by Fickett teaches that computer based promoter prediction was at most 13-54% (page 872, right column, last paragraph) effective at finding true positive promoters and that the challenge of finding . . . promoters is far from being met. FICKETT AND HATZIGEORGIOU, (1997) Eukaryotic Promoter Recognition Genome Research 7:861-878.

The state of the prior art, as exemplified by Hauschild et al (1998) Plant Molecular Biology, vol. 36, pp. 473-478) teaches that identification of poppy alkaloid pathway gene promoters is highly unpredictable and that there was an unexpectedly high species specificity of poppy alkaloid pathway regulatory regions. Hauschild found that the berberine bridge enzyme (BBE1) promoter, when operably linked to GUS, was active in only 2 out 28 plant species tested and was only able to determine this after

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undue trial and error experimentation. (See Table 2, Abstract, page 477, right column, first full paragraph). Positive control 35S – GUS constructs showed notably different results. *Id.* Thus, gene promoter identification, including promoters such as SEQ ID NO: 1 are difficult to identify, and identification is unpredictable because even if one had the sequence of the entire rice genome, including all the promoters, when put into a model system, the skilled artisan would not see any expression in many plants and thus would not discover that the pathway operon or DNA region of interest contained or was a promoter. The skilled artisan would have to depend on luck that he uses the right model system.

In the instant case, along with the absence of working examples, the relatively small amount of guidance in the specification, the unpredictability in the art and the large amount of experimentation would be necessary to achieve function balanced only against the high skill level in the art, it is concluded that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

***Claim Rejections - 35 U.S.C. §102, lack of novelty***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

35 U.S.C. §102.

13. Claims 1-4, 6-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Conner, et al. (WO/01/16307, published 30 August 2000).

Conner discloses a plant (page 44, line 5) comprising at least one promoter promoting a specific level of expression and a gene operably linked to the promoter (page 49, line 10), wherein the specificity of the promoter is determined based on the expression frequency (Example 2) of the gene including the promoter in a cDNA database (Example 2) in which the gene including the promoter is included (Example 2), and the promoter is selected as promoting desired specific expression (Example 2), wherein the gene is constitutively expressed (page 3, line 5; page 13, line 23 to page 14, line 23; page 34, line 16 to page 35, line 2), wherein the gene is specifically expressed in leaves (page 3, line 24; page 49, line 12; page 51, line 15; page 51, line 28), wherein the plant is rice (page 20, line 24), wherein the gene is a disease resistance (page 36, line 8) gene or an insect resistance gene (page 36, line 7), wherein the gene is a vitamin synthesizing gene (page 36, line 9), wherein the promoter does not drive the expression of a gene in fruit (page 51, line 24), wherein the promoter specifically drives the expression of a gene in callus (page 44, line 44; page 5, line 24),

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wherein an expression cassette comprises a promoter wherein the specificity of the promoter is determined based on the expression frequency of the gene including the promoter in a cDNA database in which the gene including the promoter is included, and the promoter is selected as promoting desired specific expression, wherein the expression cassette promotes the constitutive expression of a gene wherein the gene is constitutively expressed, wherein the gene is specifically expressed in leaves, wherein the expression cassette specifically drives the expression of a gene in leaves, wherein the expression cassette specifically drives the specific expression of a gene in callus.

Conner also discloses a callus specific promoter, expression cassette recombined therewith, and a plant transformed therewith. (page 44, line 44; page 5, line 24).

Thus, the reference discloses all the limitations of the Claimed invention.

### ***Claim Rejections - 35 U.S.C. §103, lack of obviousness***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

35 U.S.C. §103(a).

The *Graham* court set forth the factual inquiries that are applied for determining obviousness under 35 U.S.C. 103(a):

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

*Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conner, et al. (WO/01/16307, published 30 August 2000) or Conner, et al. (WO/01/16307, published 30 August 2000) in view of Draper (6031151-US, Issued 29 February 2000). The claims are broadly drawn to callus specific promoters and plants transformed therewith.

The teachings of Conner have been discussed above.

While Conner does not teach a transformed rice plant, Conner does teach rice transformation methods. (page 40, lines 1-4).

Conner also teaches that it would be advantageous to have a variety of promoters to tailor gene expression such that a gene or gene(s) is transcribed efficiently at the right time during plant growth and development, in the optimal location in the plant, and in the amount necessary to produce the desired effect. (Conner @ page 2, lines 3-7). Conner continues that callus "promoter sequences can be used for selectively modulating

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expression . . . and provide additional regulatory element diversity in a plant expression vector in gene stacking approaches". (Conner @ page 3, lines 20-30).

Draper teaches a callus specific promoter. (See abstract).

Draper also teaches that callus specific promoters can "enable the provision of more environmentally and nutritionally acceptable genetically engineered crops and foodstuffs," and that minimizing marker gene expression and therefore marker gene products in commercially grown crop plants is desirable. (Draper @ col. 1, lines 5-10, col. 2, lines 34-41).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to transform rice as taught in the many rice transformation method references cited by Conner for the purposes of driving expression with a callus specific promoter as taught by Conner or Draper to enhance target protein expression in callus or to minimize unwanted marker gene expression in foodstuffs. One skilled in the art would have been motivated to generate the claimed invention because minimizing unwanted marker gene expression is desirable as taught by Draper. One would have had a reasonable expectation of success of using such promoters because Draper was successful in monocots and rice is a monocot. Conner's successful corn(dicot) callus promoter use also supports a reasonable expectation of success. (Connor @ page 56, line 25). Accordingly, one of ordinary skill in the art would have generated the claimed invention.

**Comment**

15. SEQ ID NO: 1 is deemed free of the prior art. For SEQ ID NO: 1, the closest prior art identified through sequence searches was Sasaki, et al., 66.8% identical, found in GenEMBL Database. Accession No. AP003964 from a direct submission, published on 7/21/02.

Claims 22 and 25 are deemed free of the prior art given the failure of the prior art to teach or reasonably suggest a promoter having the sequence of SEQ ID NO: 1.

16. No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brendan O. Baggot whose telephone number is 571/272-5265. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571/272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

bob

DAVID H. KRUSE, PH.D.  
PRIMARY EXAMINER

